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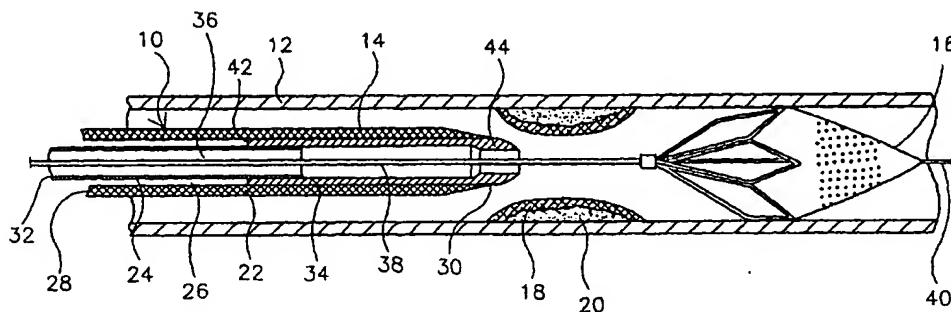
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: **HYDRAULIC CONTROLLED RETRACTABLE TIP FILTER RETRIEVAL CATHETER**



(57) Abstract: Distal protection filter (16) retrieval devices and methods of retrieving a distal protection filter. A filter retrieval catheter (10) comprise an inner tube (24), an outer tube (22) disposed over the inner tube, an annular lumen (26) disposed between the inner tube and the outer tube, and a tapered member (14) coupled to the lumen. The tapered member (14) is movable between a first position for passing a lesion and a second position retrieving a filter.



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HYDRAULIC CONTROLLED RETRACTABLE TIP FILTER RETRIEVAL CATHETER

Background of the Invention

1. Field of the Invention

The present invention pertains to catheters for retrieving a distal protection filter. More precisely, the present invention pertains to retrieval catheters having a tapered distal tip.

2. Description of the Related Art

Heart disease is a major problem in the United States and throughout the world. Conditions such as atherosclerosis result in blood vessels becoming blocked or narrowed. This blockage can result in lack of oxygenation of the heart, which has significant consequences since the heart muscle must be well oxygenated in order to maintain its blood pumping action.

Occluded, stenotic, or narrowed blood vessels may be treated with a number of relatively non-invasive medical procedures including percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA), and atherectomy. Angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire such that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated and the restriction of the vessel is opened. During an atherectomy procedure, the stenotic lesion may be mechanically cut away from the blood vessel wall using an atherectomy catheter.

During angioplasty and atherectomy procedures, embolic debris can be separated from the wall of the blood vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural and pulmonary vasculature, both of which are highly undesirable. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. Because of this debris, a number of devices, termed distal protection devices, have been developed to filter out this debris.

Brief Summary of the Invention

The present invention pertains to distal protection filter retrieval catheters. The retrieval catheter may include an inner tube, an outer tube disposed over the inner tube, a lumen disposed between the inner tube and the outer tube, and a tapered member coupled to the lumen. The tapered member may include, for example, a distal tip or a rolling membrane movable between a first position and a second position.

The first position may comprise the most appropriate position for advancing the catheter across, for example, a stent or lesion. The second position may comprise the most appropriate position for retrieving a distal protection filter. Shifting the tapered member between the first position and the second position may occur by, for example, altering fluid pressure, venting fluid, or infusing fluid into the lumen.

Brief Description of the Several Views of the Drawings

Figure 1 is a cross-section of a distal protection filter retrieval catheter disposed within a blood vessel including a tapered member in a first position;

Figure 2 is a cross-section of the distal protection filter retrieval catheter of Figure 1 having the tapered member in a second position;

Figure 3 is a cross-section of an alternate distal protection filter retrieval catheter disposed having a tapered member in a first position; and

Figure 4 is a cross-section of the distal protection filter retrieval catheter of Figure 3 having a tapered member in a second position.

Detailed Description of the Invention

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate example embodiments of the claimed invention.

Figure 1 is a cross-section of a distal protection filter retrieval catheter 10 disposed within a blood vessel 12 and including a tapered member 14 configured in a first position. Removing a distal protection filter 16 from blood vessel 12 following an intravascular procedure may be complicated by a number of factors. For example, if the intravascular procedure includes the placement of a stent 18 adjacent a lesion 20, a

retrieval catheter may catch or otherwise engage stent 18, which could lead to the displacement of stent 18. To minimize the chance of disrupting stent 18 or any other interventions that may be present adjacent lesion 20, distal protection filter retrieval catheter 10 has been designed to include a tapered member 14 that may assist passing catheter 10 past lesion 20 while causing minimal disruption of stent 18.

Catheter 10 includes an outer tube 22 disposed over an inner tube 24 and including an annular lumen 26 disposed therebetween. Outer tube 22 includes a proximal end 28 and a distal end 30. Outer tube 22 may be comprised of a polymer, stainless steel or nickel-titanium alloy hypodermic tubing, or a composite thereof. Alternatively, outer tube 22 may be generally comprised of metals, polymers, or composites thereof.

Inner tube 24 includes a proximal end 32, a distal end 34, and an inner lumen 36 extending therethrough. Similar to what is stated above for outer tube 22, inner tube 24 may be comprised of metals, polymers, or composites thereof. Inner lumen 36 may comprise a guidewire lumen adapted and configured to have a guidewire, core wire, etc. disposed therein.

Tapered member 14 may include a proximal end 42 and a tapered distal tip 44. Tapered member 14 may be coupled to lumen 26. For example, tapered member may comprise a polymeric, metallic, or composite tubular member slidably disposed within lumen 26. In addition, the position of tapered member may be maintained or otherwise altered by altering the pressure and/or the amount of fluid within lumen 26.

Tapered member 14 is movable between a first position and a second position. According to this embodiment, the first position is understood to be tapered member 14 configured such that at least a portion of distal tip 44 thereof extends beyond distal end 30 of outer tube 22. The first position may be the most appropriate position for tapered member 14 when advancing catheter 10 across stent 18 or lesion 20 toward filter 16.

Distal protection filter 16 may be coupled to a generally metallic elongate shaft 38, for example proximate a distal end 40 thereof. When using catheter 10 to retrieve filter 16 from blood vessel 12, catheter 10 may pass over shaft 38 to a location proximate

filter 16. According to this embodiment, at least a portion shaft 38 may extend through inner lumen 36.

Filter 16 and shaft 38 may generally comprise a number of configurations known to those skilled in the appropriate art. Filter 16 may be comprised of a polyurethane sheet and include at least one opening that may be, for example, formed by known laser techniques. The holes or openings are sized to allow blood flow therethrough but restrict flow of debris or emboli floating in the body lumen or cavity.

Filter 16 may be generally cone-shaped, and have a proximal and a distal end. The distal end may be a narrow, "V"-shaped end and can be fixedly secured or formed to shaft 38. The proximal end has a relatively wide opening. Alternatively, filter 16 may be cylindrical with a relatively rounded distal end.

Filter 16 operates between a closed collapsed profile and an open radially-expanded deployed profile for collecting debris in a body lumen. Filter 16 may include a collapsible proximally-tapered frame having a mouth and a plurality of longitudinally-extending ribs. In an expanded profile, the mouth is opened and the ribs extend radially outwardly to support the mouth. In an alternate embodiment, filter 16 may comprise a number of differing objects including, but not limited to, a filter, a basket, a filter basket, a sheath, a capture sheath, a capturing device, one or more struts, one or more ribs, a mesh, a net, an expandable object, a self-expanding object, and combinations thereof. A number of differing configurations of filter 16 may be substituted without departing from the spirit of the invention.

Figure 2 is a cross-section of distal protection filter retrieval catheter 10 having tapered member 14 in a second position. The second position is understood to be tapered member 14 configured so that distal tip 44 may be disposed proximal to distal end 30 of outer tube 22. The second position may be the most appropriate position for retrieving filter 16. Accordingly, when tapered member 14 is in the second position, the inside diameter of tapered member may be sufficiently sized to accommodate filter 16 and allow removal thereof from blood vessel 12.

Inner tube 24 and outer tube 22 may be configured such that distal end 30 of outer tube 22 extends distally beyond distal end 34 of inner tube 24. The length that outer tube 22 extending distally of inner tube may be sized appropriated for having filter 16 disposed therein. Shifting tapered member 14 from the first position to the second position would shift the inside diameter of catheter 10 from that of tapered member 14 or inner tube 24 to that of the inside diameter of outer tube 22. Increasing the inside diameter of catheter 10 makes it possible for filter 16 to be disposed therein, either collapsed or partially collapsed.

To shift tapered member 14 between the first and the second positions, a clinician alters the fluid pressure or vent fluid from lumen 26. For example, a quantity of fluid may be disposed within lumen 26 that exerts a force upon tapered member 14 so as to hold it in the first position. With tapered member 14 in the first position, catheter 10 may be advanced across stent 18 or lesion 20. Once catheter is positioned across stent 18, the fluid can be vented from lumen 26. Venting fluid from lumen 26 will essentially remove the force exerted by the fluid on tapered member 14 and allow it to shift to the second position. The actual shift may occur by a number of mechanisms. For example, once catheter 10 encounters filter 16, proximal movement of filter 16 into catheter 10 may exert a force on tapered member 14 in the proximal direction and, thus, shift it into the second position.

Alternatively, tapered member 14 may be biased to be in the second position (e.g., by a spring, etc.). According to this embodiment, force exerted upon tapered member 14 by the fluid may be acting to overcome the bias and hold tapered member 14 in the first position. Venting the fluid would allow the bias in position of tapered member 14 to shift tapered member 14 to the second position.

Figure 3 is a cross-section of an alternate distal protection filter retrieval catheter 110 having a tapered member 114 in a first position. Catheter 110 is essentially the same in form and function as catheter 10 except that tapered member 114 comprises a rolling membrane and that inner tube 124 and outer tube 122 are configured such that distal end 134 of inner tube 124 extends distally beyond distal end 130 of outer tube 122.

Tapered member 114 may be comprised of a polymer or combination of polymers extending between distal end 130 of outer tube 122 and distal end 134 of inner tube 124 and be generally tapered and having a relatively low profile. Tapered member 114 is in fluid communication with lumen 126. Similar to what is described above, lumen 126 may include a fluid or other means for exerting force onto tapered member 114. In alternate embodiments, tapered member 114 may be relatively inelastic or be elastic.

Similar to what is described above, tapered member 114 may be shifted between the first and the second positions by, for example, altering the fluid pressure, infusing fluid, or venting fluid from lumen 126. The first position of tapered member 114 is understood to be where at least a portion of tapered member 114 is disposed proximal to distal end 134 of inner tube 124. With tapered member 114 in the first position, catheter 110 may be advanced across stent 18 or lesion 20. Once catheter 110 is positioned across stent 18, the fluid can be infused into lumen 126. Infusing fluid into lumen 126 will exert a force on tapered member 114 and cause it to move or roll distally, and shift it to the second position.

Figure 4 is a cross-section of distal protection filter retrieval catheter 110 having tapered member 114 in a second position. The second position is understood to be a configuration of tapered member 114 wherein at least a portion thereof extends distally of distal end 134 of inner tube 124. When tapered member 114 shifts from the first position to the second position, outer tube 122 may move distally relative to inner tube 124. This movement may be due to force exerted by the fluid onto tapered member 114 being transferred to outer tube 122. Alternatively, the position of outer tube 122 may be fixed relative to inner tube 124.

It can be appreciated that the first position of tapered member 114 would be the appropriate position for advancing tapered member 114 past lesion 20 or stent 18, and the second position is the position that would be appropriate for retrieving filter 16. According to this embodiment, the second position would configure catheter 110 with an inside diameter (e.g., the inside diameter defined by tapered member 114 or outer tube 122) that is sized for having filter 16 disposed therein.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

What is claimed is:

1. A filter retrieval catheter, comprising:
an inner tube having a proximal end, a distal end, and an inner lumen extending therethrough;
an outer tube disposed over the inner tube, the outer tube including a proximal end and a distal end, wherein an annular lumen is defined between the inner tube and the outer tube; and
a tip member slidably disposed in the lumen for movement between a first position and a second position.
2. The filter retrieval catheter in accordance with claim 1, wherein a quantity of fluid is disposed within the annular lumen.
3. The filter retrieval catheter in accordance with claim 1, wherein, in the first position at least a portion of the tip member extends distal of the distal end of the outer tube.
4. The filter retrieval catheter in accordance with claim 1, wherein, in the second position comprises the member tip is disposed proximal to the distal end of the outer tube.
5. The filter retrieval catheter in accordance with claim 1, further comprising a shaft disposed within the inner lumen.
6. The filter retrieval catheter in accordance with claim 5, wherein the shaft includes a filter coupled to the shaft.
7. A filter retrieval catheter, comprising:
an inner tube having a proximal end, a distal end, and an inner lumen extending therethrough;

an outer tube disposed over the inner tube, the outer tube including a proximal end and a distal end; wherein an annular lumen is defined between the inner tube and the outer tube; and

a tip member coupled in third communication to the lumen, wherein the tip member includes a rolling member in fluid communication with the annular lumen, the rolling member adapted and configured to transition between a first position and a second position.

8. The filter retrieval catheter in accordance with claim 7, wherein, in the first position at least a portion of the rolling member is disposed proximal to the distal end of the inner tube.

9. The filter retrieval catheter in accordance with claim 7; wherein, in the second position at least a portion of the rolling membrane extends distally of the distal end of the inner tube.

10. A method of retrieving a filter from a blood vessel, comprising the steps of:

providing a catheter having a distal tip movable between first and second positions under the influence of fluid pressure;

advancing the catheter to the filter;

altering the fluid pressure to allow the tip to move between the first and the second position;

enclosing the filter at least in part within the catheter; and

removing the catheter and filter proximally from the blood vessel.

11. The method in accordance with claim 10, wherein the step of altering the fluid pressure includes decreasing the fluid pressure, and wherein decreasing the fluid pressure shifts the tip from the first position to the second position.

12. The method in accordance with claim 10, wherein the step of altering the fluid pressure includes increasing the fluid pressure, and wherein increasing the fluid pressure shifts the tip from the first position to the second position.

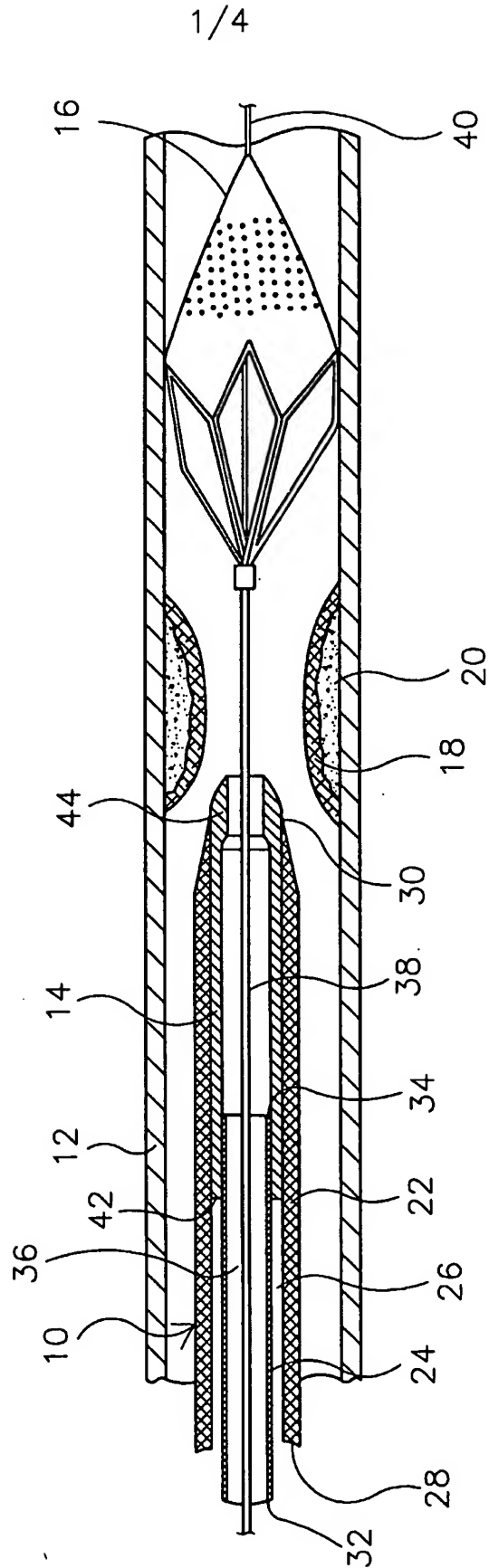


FIGURE 1

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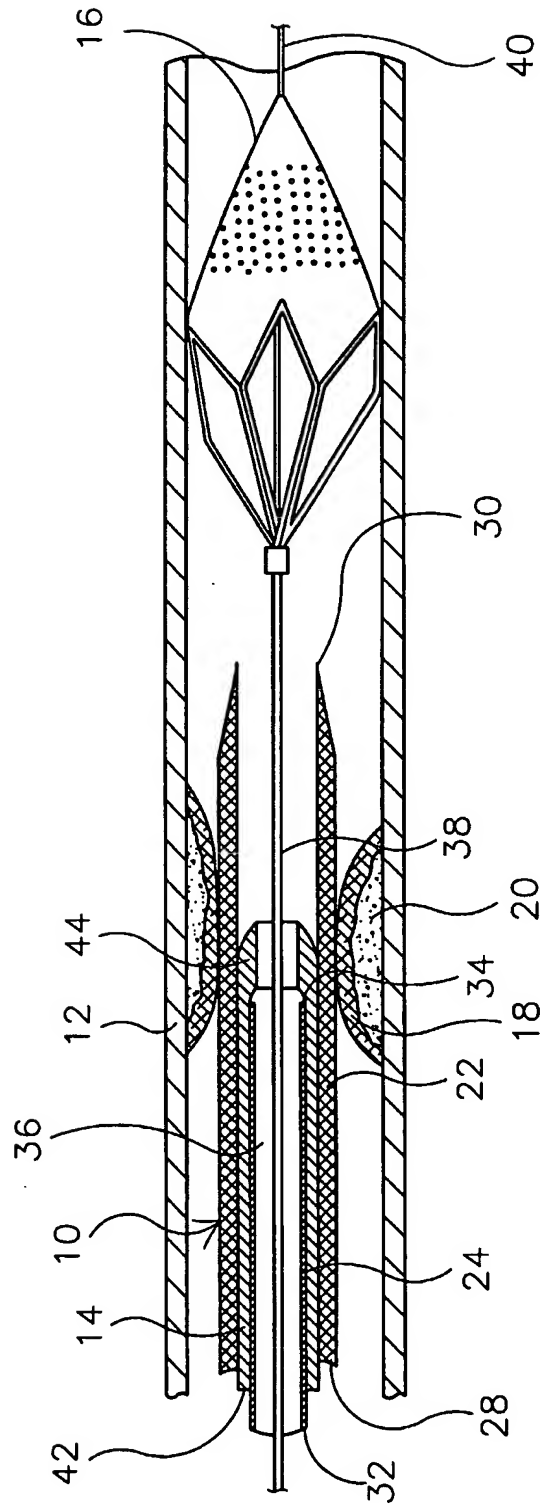


FIGURE 2

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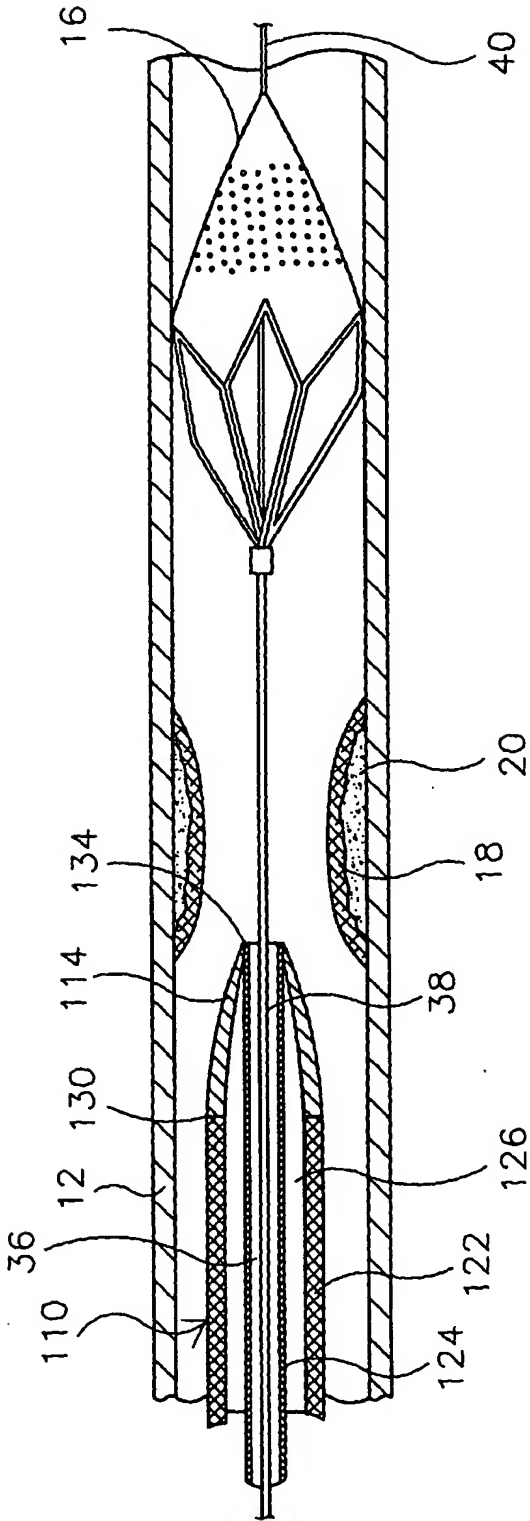


FIGURE 3

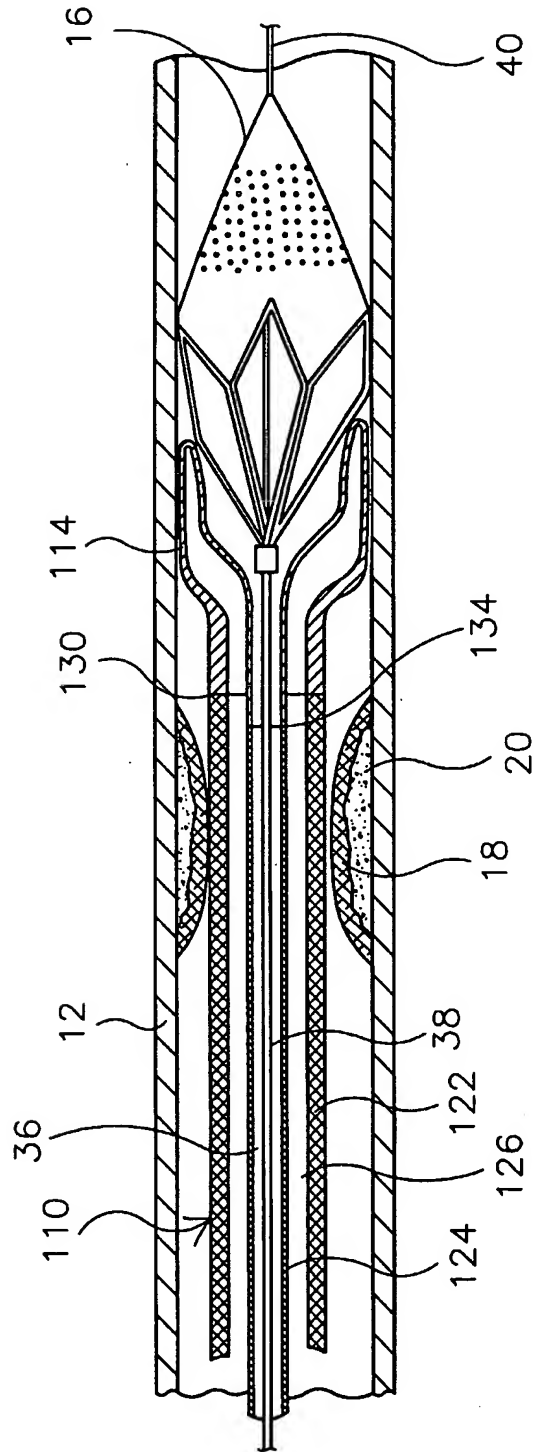


FIGURE 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/36182

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | WO 01 12082 A (GILSON PAUL ; SALVIAC LTD (IE); GRIFFIN PATRICK (IE); VALE DAVID (I) 22 February 2001 (2001-02-22) figures 3-6 | 1,3-6 |
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| X | US 6 059 813 A (SMITH SCOTT R ET AL) 9 May 2000 (2000-05-09) column 2, line 39 -column 6, line 44 column 5, line 48 -column 6, line 10 column 7, line 23; figures 1,2 --- | 7-9 |
| A | US 3 502 069 A (SILVERMAN DANIEL) 24 March 1970 (1970-03-24) abstract --- -/-- | 7-9 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

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Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/36182

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| A | US 6 152 946 A (BROOME THOMAS E ET AL) 28 November 2000 (2000-11-28) column 9, line 41 - line 58; figures 20,21 ----- | 1-9 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/36182

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10-12
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/36182

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